



45 CFR 46 107 IRB Membership

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RESEARCH



Characteristics

Qualifications

- “Professional competence”
 - Experience
 - Expertise

Representative of...

- Community attitudes
 - Promote respect for its advice and counsel in safeguarding the rights and Welfare of human subjects



Additional Requirements

Diversity of members

- Race
- Gender
- Cultural background/sensitivity





Additional Expectations

“The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.”



Additional Expectations

“The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.”

- IRB members
- Consultants



Non-scientist Member(s)

(b) Each IRB shall include at least one member whose **primary concerns are in scientific areas** and **at least one member whose primary concerns are in nonscientific areas.**



Non-scientist Member(s)

- **Scientist/Nonscientist** – Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist,
- While members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist.
- **The IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.**



Unaffiliated Member

(c) Each IRB shall include **at least one member** who is not part of the immediate family of a person who is affiliated with the institution.



Affiliation

An employee or agent of the organization registering the IRB (or a member of that person's immediate family) is considered affiliated.

Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.

An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution.

Paying unaffiliated members for their services would not make the member "otherwise affiliated" as stated in the regulations, or cause the member to have a conflicting interest.



Conflict of Interest

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.



Use of Consultants

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.



IRB Membership

- ✓ Must have at least five members
- ✓ Must have expertise and experience
- ✓ Must have diversity
- ✓ Must have a non-scientist
- ✓ Must have an unaffiliated member